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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/081,953

02/22/2002

William J. Hennen

2820-4428.2US

6427

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01/18/2011

Durham, Jones & Pinegar --
Intellectual Property Law Group
P.O. Box 4050
Salt Lake City, UT 84110

EXAMINER

CHEN, STACY BROWN

ART UNIT

PAPER NUMBER

1648

NOTIFICATION DATE

DELIVERY MODE

01/18/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/081,953	HENNEN ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7-16 and 18-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7-16 and 18-22 is/are rejected.
- 7) ☒ Claim(s) 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 1, 2010 has been entered. Claims 1, 2, 7-16 and 18-23 are pending and under examination.

Claim Objections

2. Claim 1 contains a typographical error in the phrase, "an antigen the corresponds to". Correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 7-16 and 18-22 remain rejected under 35 U.S.C. 102(e) as being anticipated by Dopson (PGPub 2002/0044942A1, "Dopson", published April 18, 2002, with priority to provisional application 60/233,400, filed September 18, 2000), for reasons of record. Applicant

indicates in the response filed September 1, 2010, that an affidavit may be filed once all other issues in this application are resolved.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 7-16 and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tokoro (US Patent 5,080,895) in view of Kirkpatrick et al. (US Patent 5,840,700, "Kirkpatrick"), for reasons of record. Applicant's arguments have been carefully considered but fail to persuade. Applicant's arguments are directed to the following:

- Applicant argues that Tokoro's admission that "the immunological functions of the transfer factor-like component...are not known", (see col. 7, lines 44-47) one would not have any certainty as to whether the transfer factor-like component would elicit a T cell mediated immune response. Applicant also continues to note that a T-cell response is critical to the production of transfer factor. Tokoro's hens were exposed to the specific bacterial antigens suggested by Tokoro, yet they did not have a T-cell response. Applicant asserts that the specific antigens disclosed by Tokoro would not have caused chickens to elicit a T-cell response.
- In response to Applicant's arguments, while exact functions of transfer factor-like component were not known, Tokoro still teaches that it is useful for treatment of

various infectious diseases (other than intestinal infectious diseases), as well as for use as additives in food, cosmetics and medicines (see col. 4, lines 5-26). One would not have had to have known about the particular functions of transfer factor-like component to have administered it as suggested by Tokoro.

- The Office has previously acknowledged that certain bacterial antigens suggested by Tokoro, such as an ETEC antigen, are not expected to induce T-cell mediated immunity in hens. The Office also acknowledges that a T-cell response is critical to the production of transfer factor. However, Tokoro does not have to teach that the antigens elicit a T-cell response. The obviousness rejection relies on Tokoro's description of a transfer factor-like component that is specific for an antigen from a pathogen, in combination with a reference that teaches an antigen/pathogen that is known to induce T-cell mediated immunity in an animal.
- For example, Tokoro fails to disclose EBV-specific transfer factor. However, Tokoro suggests the use of virtually any antigen of choice for the production of a substance containing transfer factor-like component, including those other than intestinal infectious diseases (col. 4, lines 16-18). Antigens from pollen, bacteria, viruses, molds, allergens, blood from affected animals, sperm and toxins may be used in the production of transfer factor-like component (col. 4, lines 53-57). One would have been motivated to select an antigen from a clinically significant pathogen such as Epstein-Barr virus, a known pathogen for which a vaccine is desirable to prevent mononucleosis (Kirkpatrick, col. 5, lines 7-30). By

immunizing hens with an EBV antigen, Tokoro's hens would have produced transfer factor-like component specific for EBV.

- Applicant argues that the "transfer factor-like component" produced as a result of Tokoro's method is distinct from Applicant's transfer factor. Applicant notes that Kirkpatrick teaches that transfer factors are extracted from lymphoid cells (not eggs) and that Kirkpatrick teaches away from using transfer factor from natural sources. This is in contrast to the claims which require that the egg extract contain other egg yolk proteins.
- In response to Applicant's argument, the Office notes that Kirkpatrick is relied upon for the teaching regarding the transfer factor molecule itself, and not Kirkpatrick's prescribed use of the molecule. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Conclusion

5. No claim is allowed. Claim 23 is objected to as being dependent on a rejected claim.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30), alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B. Chen/
Primary Examiner, TC1600